Minor Morbidity With Emergency Tourniquet Use to Stop Bleeding in Severe Limb Trauma: Research, History, and Reconciling Advocates and Abolitionists

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ABSTRACT Background: In prior reports of active data collection, we demonstrated that early use of emergency tourniquets is associated with improved survival and only minor morbidity. To check these new and important results, we continued critical evaluation of tourniquet use for 6 more months in the current study to see if results were consistent. Methods: We continued a prospective survey of casualties and their records at a combat support hospital in Baghdad who had tourniquets used at a combat hospital in Baghdad (NCT00517166 at ClinicalTrials.gov). Results: After comparable methods were verified for both the first and current studies, we report the results of 499 patients who had 862 tourniquets applied on 651 limbs. The clinical results were consistent. No limbs were lost from tourniquet use. Conclusion: We found that morbidity was minor in light of major survival benefits consistent with prior reports.

INTRODUCTION

Historically most emergency tourniquet use results have been bad, but we reported recently the first quality evidence that tourniquets could be lifesaving. Although prehospital hemorrhage control is held to be vital to improved trauma care¹⁻⁵ and recent American military reports indicate tourniquets appear lifesaving, 6-9 yet are controversial even on the battlefield. 8,10,11 Some military surgeons have offered limited and guarded support of tourniquets, 10,12 whereas other authors have described them as good and bad tools depending on how they were used. 13-16 For want of data and analysis, a pattern of tourniquet lessons learned and lost has been repeated on battlefields since the decline and fall of the Roman Empire. 17-19 Until recently tourniquets were considered a treatment of last resort, therefore, few clinicians accrued substantial experience with them. Lack of experience and knowledge led to morbidity and mortality in prior wars. 19 For example, some experienced surgeons felt that more limbs and lives were lost from improper tourniquet use than were saved by proper use. 20-26 Recent developments in Tactical Combat Casualty Care led by Captain Frank

Butler focused efforts aimed to save lives of limb-injured casualties on the battlefield. 3.27-30

Since the preponderance of historical data conflicted with our recent reports, changes in investigators, possibly changing mechanisms of injury and resultant wounding patterns, we felt it was imperative to see if the prior results were consistent over time. We continued with clinical research at the U.S. combat support hospital in Baghdad, Iraq, where all providers turned over in a scheduled fashion and the on-site primary investigator changed to begin another 6-month period.^{6,13,31} We hypothesized that tourniquets might cause morbidity associable with such changes. Our objective was to analyze emergency tourniquet use to assess consistency in results.

METHODS

Study Design

We aimed to see if our prior work findings on emergency tourniquet use were report consistent. If the results were consistent, then to pool data and see if there was justification to refine practical recommendations. We continued the approved protocol (Brooke Army Medical Center institutional review board). The first 6-month period began in March 2006 and the second 6-month period followed the first. There was a 4-day training period for the second author with the first author. The first author, an orthopedic surgeon with extensive experience with emergency tourniquet use, was replaced as site investigator by a registered nurse of the military's Deployed Combat Casualty Care Research Team who was new to emergency tourniquets. The investigators and hospital providers turned over simultaneously. Methods are detailed in our previous reports.^{6,13} In brief, we continued a prospective observational survey with cohort and subgroup analyses (NCT00517166 at

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Form Approved OMB No. 0704-0188 ClinicalTrials.gov). The patients were severely injured with high risk of shock, coagulopathy, and death.6 Nerve palsy at the level of the tourniquet was defined conventionally on nerve physical examination as the sensory and motor weakness of innervated muscles whose nerve was under the tourniquet, e.g., wrist drop of radial nerve palsy with arm tourniquet. Nerve palsy at the level of the wound was defined similarly except the nerve dysfunction was located distal to the tourniquet at an open wound, e.g., open proximal ulna fracture with hand intrinsic paralysis with arm tourniquet with visible ulnar nerve injury distal to the cubital tunnel. Anatomic indications were tissue lesions that risk limb exsanguination like a thigh gunshot wound with a femoral artery transection and were defined and confirmed surgically. Situational indications were predicaments where appliers choose a tourniquet as best for reasons other than the lesion, e.g., care under fire on the battlefield, and were defined and determined by appliers. The study group included 232 casualties from the first time period and 267 from the second.

We compared proportions of key variables to test consistency of between the first and current study.

RESULTS

Comparing the First and Current Study

The first and current study were similar for the number of patients (232 vs. 267), deaths (31 vs. 34), palsies at the level of the tourniquet (5 vs. 4), and limbs with major shortening (1 vs. 1; Table I). These data were similar, so the results were consistent. Since the methods and results were consistent and similar, we pooled the data to see if the power would affect results.

Study Group Demographics

The study group consisted of 499 patients. There were 559 patients included, and 60 were excluded for detainee or purposefully loose use criteria (559 - 60 = 499). The 499 patients were from 13 nations, and included 257 Iraqis and 226 Americans. The 479 males, 20 females, 16 children (<18 years old), and 5 elderly patients (>60 years old) had 651 limbs with tourniquets. Since a single tourniquet was not always effective, multiple tourniquets on a limb were sometimes required to stop bleeding. The age averaged 29 years (median, 27; range, 4–70). Follow-up averaged 36 days (range, 0.5–860 days; median, 5 days).

TABLE I. Comparison of Key Variables for the 2 Time Periods

			Time Period		p Value
Study Population Variable		Unit	First	Second	
Morbidity Rate	Palsy at Tourniquet	% of Patients	1.7	1.5	0.84
	Major Limb Shortening	% of Patients	0.4	0.4	0.92

The 651 limbs included 328 left and 323 right limbs; there were 176 upper limbs, and 475 lower limbs with tourniquets. For the 862 tourniquets with known number per limb, one tourniquet was used in 445 limbs, two tourniquets were used in 166 limbs, three tourniquets were used in 24 limbs, four tourniquets were used in 2 limbs, and five tourniquets were used in 1 limb. In this single casualty, a prehospital Combat Application Tourniquet (CAT, North American Rescue Products, Greer, South Carolina) was ineffective so an Emergency Medical Tourniquet (Delfi Technologies, Vancouver, British Columbia) was added next to the CAT but the Emergency Medical Tourniquet's cap fell off, so it was removed and another CAT and a Special Operations Forces Tactical Tourniquet (Tactical Medical Solutions, Anderson, South Carolina) were added in the emergency department (ED); in flight to Germany, the patient rebled and a Special Operations Forces Tactical tourniquet was emergently replaced on landing. Thirteen limbs had at least one tourniquet used, but the specific number of tourniquets was unknown. If we say these 13 limbs had only one tourniquet per limb, then the total number of tourniquets was 875. The body regions (forearm, arm, leg, thigh) where the tourniquets were applied to the 651 limbs included 436 thighs, 162 arms, 46 legs, 13 forearms, 8 limbs where the tourniquets were applied above and below the major joints (knee or elbow), and 2 limbs were unknown.

Prehospital and ED Settings of Emergency Tourniquet Use

Tourniquets were more commonly used in the prehospital than hospital setting as 85% of the patients were first treated with tourniquets before they arrived at the ED. The patients that had their first tourniquet applied to any limb in the hospital numbered 76, 38 in each of the two time periods, and the number of prehospital patients was 194 and 228, respectively, in the first and current study while one patient's setting was unknown in the current study. The mechanisms of injury were a broad spectrum of penetrating, blunt, crush, and thermal injury, or combinations thereof. Injuries (72%) were primarily due to explosions. Morbidity was consistently minor between the time periods (Table II). Furthermore, the demographics, the mechanisms of injury, the associated injuries, the overall injury severity, and comorbidities between the two groups were similar (p > 0.05) in the two time periods, so the two groups themselves were comparable.

Thirteen casualties (13 limbs) had so-called paradoxical bleeding in that the tourniquet use eventually led to increased not decreased bleeding. We witnessed the general progression in these cases as follows: initial hemorrhage control and persistence of the distal pulse, increase in limb girth over time, venous engorgement distally, decreased compressibility of distal veins, swelling and edema, wound blood pooling, expanding hematoma formation and enlargement, compartment syndrome and occasional loss of distal pulse until fasciotomy, and loss of hemorrhage control.

TABLE II. All-cause Morbidity in Casualties with Tourniquet Use

	Study				
Morbidity	First 309 Limbs	Second 342 Limbs	Total 651 Limbs	Rate for All 651 Limbs (%)	
Amputation	103	127	230	35	
Fasciotomy	100	48	148	23	
Clot	15	6	21	3	
Myonecrosis	6	4	10	1.5	
Palsy at Tourniquet	5	4	9	1.4	
Acute Renal Failure	6	1	7	1	
Significant Pain	1	0	1	0	
Rigor	1	0	1	0	
Sum	237	190	427	65	

Patients had 0-3 morbidities per limb. The amputations in the table are the sum of traumatic injuries, surgeries, and morbidities.

Overall, 85% of the 498 patients with known site of use were prehospital, 100% (8/8 patients with 9/9 limbs) of patients with nerve palsy at the tourniquet had prehospital use. However, of ED patients, 0% (0/76) had nerve palsy at the tourniquet. Overall, 24% (162/665) of the body regions where the tourniquets were used were arms, but in the group with nerve palsy at the tourniquet, 40% (6/15 limbs in 6/15 patients) were arms, a finding consistent with elective tourniquet use in limb surgery.³² Wound palsies also showed a predominance (64%, 9/14 limbs in 9/14 patients) of arms. Most (82%) of the nerve palsies were in the arm.

Of the 9 limbs (9 patients) with nerve palsy at the tourniquet, 2 limbs (2 patients) had an unknown number, and all 7 with known numbers had only one prehospital tourniquet. In contradistinction to the 7 limbs (7 patients) with single prehospital tourniquet use and nerve palsy at the tourniquet, none of the 93 limbs with side by side (more than one used by the side of the first) use had nerve palsy at the tourniquet. The nerve palsy rate at the tourniquet ranged from 0% to 4% by body region (forearm 0/13, thigh 2/436, leg, 1/46, and arm 6/162). The overall rate of side-by-side use was 20% (93 of 461 limbs). There were also 453 limbs with one prehospital tourniquet that did not have nerve palsy at the tourniquet. Given that most patients were severely injured and had distracting associated injuries including penetrating muscle trauma and bony fractures, no patient diagnosed with a nerve palsy from a tourniquet complained of weakness or had known that they had a nerve palsy until they were clinically examined then told so. All nerve palsies at the level of the tourniquet resolved within 3 minutes to 3 days except in one Iraqi transferred with incompletely resolved nerve palsy on the third day. Tourniquet duration was not associated with nerve palsy in that those casualties with greater than 4 hours use had none. These findings converge on the point that side-by-side prehospital tourniquet use may decrease palsy risk.

DISCUSSION

Minor Morbidity Was Consistent Between the First and Current Study

Minor morbidity risk was found again with widespread tourniquet use as it was in our first study. Some morbidity such as nerve palsy were temporary, and the rates of morbidity were low (<2%). No patient had a permanent morbidity solely from tourniquet use. The risk of morbidity was minor in light of the severity of injury.¹³ With new patients and providers the consistent data increases confidence and generalizability of this finding. Given minor morbidity risk in light of major lifesaving benefit, the policy of encouraging emergency tourniquet use in our situation remains warranted. Pooling did not affect the findings of the first study despite additional power. First aid recommendations are now based on more than our prior reports.

The Venous Tourniquet Risks Morbidity in Emergency Use

Arterial tourniquets used snug and proximal to the wound are the right way to use emergency tourniquets, and venous, loose, distal, or upside down tourniquet use are ineffective for hemorrhage control. Tourniquet use in emergencies at the minimum tension to control hemorrhage has been recommended without mentioning intent to occlude veins or arteries,33 and no explanation was offered why venous occlusion and not arterial occlusion might be beneficial in light of the contrary evidence from elective surgery.34 In elective limb surgery and in emergency care of major limb trauma, occlusion of the veins with a tourniquet and not the arteries can control hemorrhage for a few minutes, but soon vein engorgement and bleeding recurs distal.^{6,13} Persistence of venous tourniquets can lead to paradoxical bleeding in that the tourniquet can make the bleeding worse than would occur without the tourniquet,35 and 13 of our casualties demonstrated this phenomenon. These 13 cases of venous tourniquets we observed appeared to occlude deep and superficial veins. Although pressure dressings seemed to act like venous tourniquets, they used less pressure than tourniquets and seemed to occlude only superficial veins. Venous tourniquets pool blood in the distal limb as in phlebotomy, engorge the distal limb, drain core blood, and worsen shock³⁶ and are associated with expanding hematomas and compartment syndrome. 13 In volunteers and trauma patients, venous tourniquets to limbs within 10 minutes caused venous congestion, extravascular swelling of the distal limb, a decrease of 29% in total core blood volume, decrease systolic blood pressure from 5 to 25%, and hypotensive shock in most cases. 36,37 Venous tourniquet use for an uninjured limb is a diagnostic test for incipient shock, i.e., a patient at risk for hemorrhagic shock is reliably worsened into shock within about 6 minutes.36 Also, in elective orthopedic surgery inflating the tourniquet fast helps limit the time that the veins are occluded and the artery is not while the tourniquet is inflated.³⁴ The quantity and quality of evidence against emergency venous tourniquets

is strong enough to recommend that they must be assiduously avoided (Table III).

An example of how not to use tourniquets was outlined by research stimulated by World War I and the Medical Research Councils of the United Kingdom and United States wherein tourniquets could cause shock with prolonged use in uninjured animals.38,46-49 The time lag from tourniquet release after prolonged use to shock onset was long and simultaneous with plasma loss into reperfused limbs. 38,46-50,51 The reliable death of animals with such use was an experimental model for some years, and unfortunately similar results were seen when two Japanese clinician–researchers killed two uninjured American prisoners of war by using tourniquets for prolonged times and then releasing them and observing shock onset and death.⁵⁰ In 1943, the National Research Council recommended consideration of amputation before tourniquet release in situations of sustained tourniquet use to stop bleeding (apparently >3 hours of warm ischemia)⁵² since such timing of amputation improved survival in animals. 48 Clinical experience of patients with >4 hours (sometimes more than 6-8 hours) of tourniquet use has been without need for amputation, 6,7,53,54 and cool ischemia harms limbs less than warm ischemia. The tourniquet was abandoned eventually as a shock model because it led to concomitant problems of hypovolemic shock, hemorrhagic shock, septic shock, potassium intoxication, and death after tourniquet release. 36,51,55 Our experience with warm ischemia more than 4 hours is 9 limbs, and no patient had these problems, but their records and data are not detailed enough to draw further conclusions. We detailed a case from Afghanistan that had over 16-hours tourniquet duration of cool ischemia without tourniquet morbidity.54 Tien et al7 described another case with prolonged use without morbidity in Afghanistan.

Nerve palsy under tourniquets, a well-studied topic, is mainly risked by high under-tourniquet pressure especially at the tourniquet edges and to a lesser degree ischemic duration.³⁴ Both pressure amplitude and gradient are associated positively and specifically with peripheral nerve deformation, structural

TABLE III. Venous Tourniquet Table Problems In order of Their Clinical Appearance

Venous Tourniquet Problems	References
Persistent Distal Arterial Pulse With Continued Core	36,38,39,40
Blood Loss	
Distal Venous Distension, Engorgement, Venous	14,41
Hypertension	
Distal Blood Pooling, Expanding Wound Hematomas,	13,14
and Need for Debridement	
Loss of Fluid From Plasma Into Tissues Distally and	13,25,42
Distal Limb Swelling and Edema	
Increased Pressure in Distal Tissues Risking	13,41,43
Compartment Syndrome, Necrosis, and Fasciotomy	
Continued Hemorrhage Often Paradoxically Worse	20,24,35,40,44
Than With No Tourniquet and Sometimes	
Difficult to Control	
Shock From Hypovolemia and Hemorrhage	36,38
Death	45,44

damage, conduction abnormality, and tourniquet palsy.⁵⁶⁻⁵⁹ In elective limb surgery with tourniquets, nerve palsies largely occur in the arm.³² Intraneural pressures above 500 mm Hg cause an intussusception-like telescoping within the nerve, which is usually worse at the proximal edge of the tourniquet where the pressure gradient is most.^{34,56} Given the known susceptibility of nerves to pressure injury,32,34 the known attenuation of pressure under a tourniquet with increasing tissue depth, 34,57-59 the proximity of susceptible arm and leg nerves to the skin, and the body regions with high nerve palsy risk with emergency tourniquets evidenced in the present report is understandable. Most nerve palsies were in the arm in the present survey whether at the tourniquet or wound. There may be a few reasons for this. There may be an anatomic risk (relatively large nerves adjacent to bone that are more frequently damaged at the wound by penetrating trauma compared with the lower limb), the small girth with only one bone permit more effective mechanical compression from tourniquet tightening than the high girth thigh or two-bone limb segments, and upper extremity palsies may be easier to detect clinically than lower limb palsies. Given that the science from elective tourniquet use indicates that the excessive mechanical pressure (amplitude and gradient) is the main risk for tourniquet palsy, and prehospital tourniquet use was associated with all our tourniquet palsies, over-tightening by prehospital appliers may be a way the patients' risked palsy. Training changes may help appliers learn the right amount of tightness. Although lifesaving benefits clearly outweighed morbidity risks, more research needs to be done to clarify this issue. Tourniquet duration is mainly associated with muscle injury as muscle is sensitive to ischemia duration, and muscle weakness is grossly confused with nerve palsy unless clinicians perform a careful examination. Within the routine pressures and durations seen clinically, nerves are sensitive to pressure and not duration, whereas muscle is sensitive to duration and not pressure.56-59

How Is That We Find Major Benefits Yet Others Have Banned Tourniquets?

Pro and con tourniquet arguments can be reconciled with a change in thinking that tourniquet best practice is not a question of if we use them or not but how and when do we best use them. In other words, current best practice has several essential features without which clinical failure appears likely. Tourniquet abolitionists banned them when they were poorly designed, used for the wrong patient at the wrong time, or they were used in the wrong way. In a pivotal battle health care analysis, Mabry et al60 analyzed the survival rate of casualties with and without tourniquet use and recommended more tourniquet use on the battlefield which was further developed by the Tactical Combat Casualty Care Committee and Butler.²⁷ The US Army later tested devices to determine the best design available. 29,30 Most limb-injured casualties do not need tourniquets, but in the small group of severely injured casualties supporters of tourniquet use recommend that for best practice, the right patient needs the right device at the right time

used in the right way. If limb-injured casualties with emergency tourniquet use had no compressible bleeding that was potentially lethal, then we expected no survival benefit beyond a pressure dressing with elevation yet morbidity was potentially increased. In our current experience we saw that wrong devices (too narrow, leaked, slipped, loosened, wore out or malfunctioned) failed. Tourniquets used after the patient bled to death, lost vital signs, or were in shock were applied too late and led to 10% survival, whereas early use led to 90% survival.⁶ Devices put on upside down, misplaced distal to the wound, broken from incorrect use, or used as a venous tourniquet risked morbidity or failure without clinical benefit. These findings all converge on an idea that tourniquet knowledge should include scientific design, adequate laboratory testing, clinical research, doctrine refinement based on evidence. and population-specific training of potential users. If decision makers find their constituents are at risk of lethal limb bleeding and the knowledge, testing, research, doctrine, and training are adequate, then emergency tourniquet use seems prudent. Lack of any one of these essentials appears to risk poor results as evidenced in prior wars and conflicts. 19,24-26,45,61 We have studied each of these essentials over the last several years, and the comprehensive approach to the multifaceted tourniquet issue has led to good results in four countries. 7-9,13,62

Sir Reginald Watson-Jones, influential author, editor, and surgeon to England's king, sat on the War Wounds Committee of the Medical Research Council, which studied hospitalized survivors during World War II, and his textbook of orthopedics (15 editions and reprints over five decades starting in 1940) abolished first aid tourniquets because he saw misuse and morbidity.^{22,23} He, senior orthopedic consultant to the Royal Air Force at a rear hospital near London, necessarily saw only survivors, and he was knighted for his effective rehabilitation services. However, where you stand depends on where you sit. R.T. Grant of the Traumatic Shock Committee's Clinical Research Unit of the same Council at the same time studied limb-injured patients (civilian and military) that lived or died early at the first hospital (in contradistinction to Watson-Jones' tertiary Liverpool Royal Infirmary). Shock mainly from prehospital hemorrhage was lethal and common in the limb injured, whereas hemorrhage control and adequate resuscitation saved lives as seen by researchers in the resuscitation bays, operating theaters, and wards of the most forward hospital.5,63,64 In the 1940 Dunkirk evacuation across the English Channel to surgical care in England, prehospital death rates were high and survivors risked tourniquet complications because of long evacuations. The views of both committees are valid, but the patients of one were not the patients of the other. One saw survivors and the other saw also non-survivors. Our patients were both prehospital and hospital, and we specifically looked at tourniquet use in hundreds of patients to reconcile the two views. The whole view includes all survivors and non-survivors. Lacking one creates a false viewpoint and leads to the wrong conclusion. In our setting, our findings indicate that R.T. Grant's and the Traumatic Shock

Committee's emphasis on hemorrhage control was correct. Our experience encompasses the findings of both committees and other clinician—authors that found risk with tourniquets, but we measured great clinical benefit and little risk in our experience with 499 patients.

For example of a misconception, military orthopedists reported that in their experience, traumatic amputations rarely bleed. 10 We have seen such patients that have stopped active external bleeding, but when you measure blood loss (from the patient's perspective) and look at hundreds of amputation patients, they usually bleed a lot and often require massive transfusion.^{37,64-67} They bleed the most of all casualties that survive to get to the first hospital.37,65 The bleeding is not limited to that observed at one point in time by one provider, but blood is left at the injury scene and throughout extrication, transport, emergency bays, operating theaters, and intensive care wards.⁶⁴ The amount of blood lost from limb-injured casualties is commonly underestimated, 37,64,65 and evidence indicates that how tourniquets control hemorrhage and affect outcomes. 6,13,39-44 If a health care system cannot evacuate patients quickly or does not look at all patients injured (some who die prehospital), then poor results occur. Instead of banning prehospital providers from trying to save lives with one of the rare tools shown to save lives for limb-injured patients, the U.S. military changed the device, training, and doctrine.

Limitations of this present morbidity report are that we do not have long follow-up or detailed records of aftercare for every patient. Although association is not causation and multiple confounders complicate tourniquet use, possible study designs of high scientific merit are ethically problematic. Future research needs include analyses of long-term follow-up, study at other sites or in other settings, study of first aid education or training, and further trend analysis of performance. It is currently unclear if apparently higher prehospital use rates and lower miss rates are a trend. Specific low incidence morbidities such as fasciotomy and amputation that occur at low rates may require a database study of large cohorts for the whole war to detect if there is increased risk with tourniquet use. We aim to address some of these topics later.

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